



CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
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PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT INSTRUCTIONS

Purpose of Self-Inspection Report

The Pharmacist-in-Charge (PIC) and all pharmacists on duty are responsible for ensuring that their pharmacies comply with all state and federal laws governing pharmacy practice. The primary purpose of this form is to guide you through a self-inspection that will help you identify and correct areas of non-compliance with state and federal law. Board inspectors will also use the completed form to evaluate the pharmacy's level of compliance.

When a Board inspector identifies an area of deficiency, he or she may issue a Deficiency Notice. The PIC is required to respond in writing. Identifying and correcting an area of non-compliance *before* the Board inspection can eliminate the Deficiency Notice. *Note that neither the self-inspection nor Board inspection evaluates your compliance with all the laws and rules of the practice of pharmacy.*

When conducting your self-inspection, it is important to take the time to review the relevant sections of law and regulations and then to personally verify that your pharmacy is in compliance. Avoid *assuming* that your pharmacy is compliant even if "that's the way it has been for years." Note that not having (or not being able to readily retrieve) required documents and records is a common deficiency cited during unannounced inspections. Maintain all such documents in a well-organized manner, such as a binder, and accurately describe the location(s) of the required documents on your *Self-Inspection Report*. If the required documents are readily available to the inspectors, even when you are not present during the inspection, you can reduce your chance of receiving a Deficiency Notice in this area.

If you have questions during your self-inspection, you may contact an inspector by emailing customerservice.dpr@state.de.us or call (302) 744-4500.

When to Complete Self-Inspection Report

The PIC of a Delaware-licensed community pharmacy must complete this *Pharmacist-in-Charge Self-Inspection Report*:

- within 30 days of your first being designated as PIC, **and**
- by February 1 of each year while you continue as the PIC.

Section 3.1.2.7 of the Board's [Rules and Regulations](#) describes this requirement. Failure to complete the *Pharmacist-in-Charge Self-Inspection Report* when required, as explained above, may result in disciplinary action.

Completing and Retaining the Report

- ☐ Complete all items on the [self-inspection report form](#).
 - All items are required unless the item states otherwise.
 - The form provided online is fillable and saveable on your computer. However, it is suggested that you print out the form complete it by hand as you inspect the various aspects of your pharmacy. If you wish, you may then transcribe your responses to the fillable form.
 - Carefully confirm whether or not you are compliant and mark the appropriate box to the right of each item.
 - The correct answer to some questions may be "no". Do not mark an item "yes" unless the answer is "yes."
- ☐ Review the report with your staff pharmacists, technicians and interns.
- ☐ Correct any deficiencies noted. Explain what corrective measures you took and note the date of correction next to the appropriate question.
- ☐ **Sign** the completed report form.
 - **If you completed the form on your computer, you must print it out and sign it.**
- ☐ Retain the completed and signed printout of the form on-site at the pharmacy so that it is immediately available for inspection at all times, even if you are not present when an unannounced inspection occurs.
 - Retaining a copy of the completed form on your computer is **not** sufficient.
 - **Do not mail the completed form to the Pharmacy Board office.**



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PHARMACIST-IN-CHARGE SELF-INSPECTION REPORT

Date PIC Self-Inspection was performed: ____/____/____

PHARMACY INFORMATION

1. Name of Pharmacy (as shown on license): _____
2. Delaware Pharmacy License Number: A3 - _____ Controlled Substances Registration PH - _____
3. DEA Registration #: _____
4. **Location Address:** _____

Street (No PO Boxes)

City State Zip
5. Phone: _____ Fax: _____ Email: _____

6. Enter hours of operation:

	PHARMACY DEPARTMENT HOURS				STORE HOURS					
Weekdays	_____	AM	to	_____	PM	_____	AM	to	_____	PM
Saturday	_____	AM	to	_____	PM	_____	AM	to	_____	PM
Sunday	_____	AM	to	_____	PM	_____	AM	to	_____	PM
Holidays	_____	AM	to	_____	PM	_____	AM	to	_____	PM

PHARMACY PERSONNEL INFORMATION

7. PIC Name (as shown on license): _____ Delaware Pharmacist License No A1 - _____
8. Enter date (month/day/year) that you became PIC for this pharmacy: _____

9. List all other registered pharmacists who will be dispensing at the Pharmacy.

FULL NAME	LICENSE NUMBER
	A1- _____
	A1- _____
	A1- _____
	A1- _____
	A1- _____
	A1- _____
	A1- _____

10. List all support personnel including pharmacy technicians, pharmacy interns, and pharmacy students and any certificate number, if available.

FULL NAME	CERTIFICATE NUMBER

PHARMACY PERSONNEL INFORMATION, Continued

11. Answer the following questions about supportive personnel. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are all supportive personnel under immediate supervision of a pharmacist? (24 Del. C. §2507)? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Do the pharmacy technicians perform only tasks permitted by Section 19.2 of the Pharmacy Rules and Regulations ? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the schedule for technical support available during all pharmacy operation hours as described by Section 3.8 of the Pharmacy Rules and Regulations ? Yes <input type="checkbox"/> No <input type="checkbox"/>	

RECORDS, REFERENCE MATERIALS AND OTHER DOCUMENTS

12. List where each of the following items is located inside the pharmacy. *Be as specific as possible.*

RECORD	LOCATION
Current Delaware laws, regulations and alerts (if not electronic):	
PIC Self-Inspection Reports for last three years	
Current written biennial controlled substance inventory	
Schedule II-V invoices for last three years	
Completed CII order forms (DEA form 222) for last three years	
Current CPR cards and immunization certification documents	
Support personnel training manual and documentation of training	

13. Answer the following questions about reference materials. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are reference materials current and available in either hard copy or electronic form? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Do the reference materials include all of the following as required by the sections of the Pharmacy Rules and Regulations shown? <ul style="list-style-type: none"> Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed to patient (Section 3.3.2.1)? Yes <input type="checkbox"/> No <input type="checkbox"/> Provide information helpful in the counseling of patients on the use of drugs dispensed (Section 3.3.2.2)? Yes <input type="checkbox"/> No <input type="checkbox"/> Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice (Section 3.3.2.3)? Yes <input type="checkbox"/> No <input type="checkbox"/> Include a list of therapeutic equivalents for drugs dispensed (Section 3.3.2.4)? Yes <input type="checkbox"/> No <input type="checkbox"/> Include current Delaware and federal laws and regulations governing pharmacy and controlled substances (Section 3.3.2.5)? Yes <input type="checkbox"/> No <input type="checkbox"/> Provide any other information necessary to the safe and effective practice of pharmacy for the specific practice setting (Section 3.3.2.6)? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

PHARMACY POLICIES & PROCEDURES

14. In addition to location, list policy number and page where each of the following is found.

POLICY/PROCEDURE	LOCATION	POLICY NUMBER & PAGE
Dispensing of pharmaceuticals		
Policy for monitoring & removing recalled, outdated drugs		
Automated dispensing systems		
Delegation for authority when PIC not available		
Compounding		
Vaccinations		
Quality assurance		
Long term care		

LICENSES & PERMITS

15. Respond to each of these questions about licenses and permits. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
<p>Have you verified that all wholesalers from which you purchase medication are registered in Delaware? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Enter names and registration numbers of primary and secondary wholesalers: Primary: _____ Secondary: _____</p>	
<p>Are all pharmacists, technicians and interns aware that they should report arrests, convictions and suspected and known violations to the Board? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>Are each of the following items posted, displayed or plainly visible?</p> <ul style="list-style-type: none"> • Current Federal and State Registrations/permits? Yes <input type="checkbox"/> No <input type="checkbox"/> • Current licenses of the pharmacists that practice at this location? Yes <input type="checkbox"/> No <input type="checkbox"/> • Sign with the name of pharmacist on duty and name of the PIC? Yes <input type="checkbox"/> No <input type="checkbox"/> • Sign stating that medication errors may be reported to Board of Pharmacy? Yes <input type="checkbox"/> No <input type="checkbox"/> • Sign stating that patient can request lot and expiration date of medication at the time Rx is filled? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

PHYSICAL FACILITIES Section 3.4 of the Pharmacy [Rules and Regulations](#)

16. Respond to each of these questions about the pharmacy facility. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
<p>Does the pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices including sink with hot and cold water, shelves, refrigerator/freezer, narcotic cabinets and safes and counter areas which are adequate to avoid crowding? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>Is temperature monitored and maintained (keep logs for refrigerator and freezer)?</p> <ul style="list-style-type: none"> • Room temp maintained at (59°-86°F) Yes <input type="checkbox"/> No <input type="checkbox"/> • Refrigerator temperature maintained (36°- 46°F) Yes <input type="checkbox"/> No <input type="checkbox"/> • Freezer temperature maintained at (-13°-14°F) Yes <input type="checkbox"/> No <input type="checkbox"/> 	
<p>Is the pharmacy area, kept clean and free of clutter (including refrigerator, sink, counting trays, automated dispensing machines, floors, etc)? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>Does pharmacy have all the required equipment and is the equipment in good working order? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
<p>Is there adequate key control (24 Del. C. §2533)?</p> <ul style="list-style-type: none"> • Is the key in possession of the pharmacist only? Yes <input type="checkbox"/> No <input type="checkbox"/> • Is the procedure for storage and documentation of use of spare key is such to prevent authorized access? Yes <input type="checkbox"/> No <input type="checkbox"/> • Describe the procedure used: _____ _____ _____ 	
<p>Do the building standards and security meet the requirements of Sections 3.5 and 3.6 of the Pharmacy Rules and Regulations?</p> <ul style="list-style-type: none"> • Is a minimum of nine square feet partitioned area available for counseling? Yes <input type="checkbox"/> No <input type="checkbox"/> • Is the counseling area set apart by 5-foot dividers on two sides? Yes <input type="checkbox"/> No <input type="checkbox"/> • When prescription department and store hours are different, is a floor-to-ceiling physical barrier used? Yes <input type="checkbox"/> No <input type="checkbox"/> • Is the "No professional services rendered" sign posted when the prescription department is closed? Yes <input type="checkbox"/> No <input type="checkbox"/> • Are filled prescriptions stored only in the department or a secured storage area? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

PATIENT COUNSELING Section 5.2 of the Pharmacy [Rules and Regulations](#)

17. Respond to each of these questions about patient counseling. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
How is a new prescription identified as requiring counseling for new and refill? _____	
Is a patient's refusal/acceptance of counseling documented? Yes <input type="checkbox"/> No <input type="checkbox"/> Describe type of record kept: _____	
Does the record indicate who made the offer to counsel? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the record indicate who counseled the patient? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is written information also provided? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is counseling conducted in a confidential manner? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are the following included with all prescriptions that are delivered to the patient? <ul style="list-style-type: none"> Written information about the prescription? Yes <input type="checkbox"/> No <input type="checkbox"/> Phone number and hours that a pharmacist is available to answer questions? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

COMPOUNDING PHARMACY Section 5.1.6 of the Pharmacy [Rules and Regulations](#)

18. Respond to each of these questions about patient counseling. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is all compounding (including reconstituting antibiotics) performed only by the R.Ph.? Yes <input type="checkbox"/> No <input type="checkbox"/> If no , is a log maintained showing the identity of the compounding person? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If compounding is done by support personnel, does R.Ph. check each step? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the pharmacy performing sterile compounding? Yes <input type="checkbox"/> No <input type="checkbox"/>	

REPACKING PHARMACY Section 6.3 of the Pharmacy [Rules and Regulations](#)

19. Respond to each of these questions about repacking. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is the pharmacy performing re-packing? Yes <input type="checkbox"/> No <input type="checkbox"/> If no , skip to PATIENT PROFILES section.	
When repackaging is done, does the log show date repacked, control number, expiration date, name and strength of drug, person who prepared it? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If not repacked by an R.Ph., is there notation of the pharmacist's check? Yes <input type="checkbox"/> No <input type="checkbox"/>	

PATIENT PROFILES Section 5.1.10 of the Pharmacy [Rules and Regulations](#)

20. Answer each of these questions about patient profiles. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
What type of profile do you use? <input type="checkbox"/> Manual <input type="checkbox"/> Computerized	
Are profiles checked prior to dispensing new and refill prescriptions? Yes <input type="checkbox"/> No <input type="checkbox"/> If no , explain when profiles are checked: _____	
Check what you record on profile: <input type="checkbox"/> Refills <input type="checkbox"/> Prescriptions Only <input type="checkbox"/> Both Refills and Prescription	
Who performs the data entry (Rx, profile)? <input type="checkbox"/> R.Ph. <input type="checkbox"/> Support Personnel	
Are profiles kept for at least one year from date of last entry in profile? Yes <input type="checkbox"/> No <input type="checkbox"/>	

PATIENT PROFILES, Continued

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Do profiles include all of this information: <ul style="list-style-type: none"> • Patient last and first name, address, phone number Yes <input type="checkbox"/> No <input type="checkbox"/> • Patient age or DOB Yes <input type="checkbox"/> No <input type="checkbox"/> • Prescriber's name and, for controlled substances, DEA # Yes <input type="checkbox"/> No <input type="checkbox"/> • Original dispense date, prescription number, number of refills Yes <input type="checkbox"/> No <input type="checkbox"/> • Documentation of patient's refusal or acceptance of counseling Yes <input type="checkbox"/> No <input type="checkbox"/> • Allergy information and chronic diseases Yes <input type="checkbox"/> No <input type="checkbox"/> • If the answer to allergies and/or chronic diseases is "none," is "none" shown on the patient profile? Yes <input type="checkbox"/> No <input type="checkbox"/> • Documentation of any information that the patient refused to provide Yes <input type="checkbox"/> No <input type="checkbox"/> • Initials of dispensing pharmacist Yes <input type="checkbox"/> No <input type="checkbox"/> • Pharmacist comments related to OTC use? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

AUTOMATED DATA PROCESSING SYSTEM (ADPS) Section 5.1.12 of the Pharmacy [Rules and Regulations](#)

21. Answer each of these questions about data processing. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Who is authorized to enter the ADPS? _____	
What is the method of entry for each authorized person (e.g., individual access code, general access code)? _____	
Would another pharmacist or support person be able to enter prescription? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If there is a general access code, can the person who entered the data be identified? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is computer used for other store functions? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does data entry of patient profiles comply with regulation? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does data entry of prescription information comply with regulation? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does data entered identify the responsible pharmacist(s) for each step in the dispensing process? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does data entered remain online for at least one year from last entry? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is data entered from one through three years ago available within five days? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If pharmacy records of the distribution, receipt, and dispensing of controlled substances are maintained centrally, is a copy of the letter notifying the DEA available? Yes <input type="checkbox"/> No <input type="checkbox"/>	

AUXILIARY RECORD-KEEPING SYSTEM Section 5.1.12.5 of the Pharmacy [Rules and Regulations](#)

22. Answer each of these questions about auxiliary record-keeping systems. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is an auxiliary record-keeping system available if ADP is inoperative? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the auxiliary record-keeping system ensure that all renewals are authorized? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the auxiliary record-keeping system give you the ability to enter prescriptions dispensed and renewed while the ADP is down? Yes <input type="checkbox"/> No <input type="checkbox"/>	

CONTAINERS

23. Answer each of these questions about containers. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are medications dispensed in containers which comply with USP requirements? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are child-resistant containers used? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is permission to use regular containers (no safety cap) documented? Yes <input type="checkbox"/> No <input type="checkbox"/>	

LABELING [24 Del.C. §2522](#)

24. Answer each of these questions about labeling. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Do prescription labels show all of the following? <ul style="list-style-type: none"> • Prescription number Yes <input type="checkbox"/> No <input type="checkbox"/> • Patient name Yes <input type="checkbox"/> No <input type="checkbox"/> • Specific directions (no "as directed" prescriptions) Yes <input type="checkbox"/> No <input type="checkbox"/> • Drug name & strength Yes <input type="checkbox"/> No <input type="checkbox"/> • Prescriber name Yes <input type="checkbox"/> No <input type="checkbox"/> • Date of dispensing Yes <input type="checkbox"/> No <input type="checkbox"/> • Appropriate auxiliary labels Yes <input type="checkbox"/> No <input type="checkbox"/> • Name and address of dispensing pharmacy Yes <input type="checkbox"/> No <input type="checkbox"/> 	

COPY EXCHANGE PHARMACY Section 5.1.11 of the Pharmacy [Rules and Regulations](#)

25. Answer this question about copy exchange. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Do copy prescriptions received and given contain necessary information? Yes <input type="checkbox"/> No <input type="checkbox"/>	

IMMUNIZATIONS Section 14.0 of the Pharmacy [Rules and Regulations](#)

26. Answer this question about immunizations administered at the pharmacy. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Is the pharmacy doing immunizations? Yes <input type="checkbox"/> No <input type="checkbox"/> If no, skip to the DISPENSING PHARMACY section.	
Is there proof available onsite that each immunizing pharmacist meets the educational requirements, including current CPR certification, two hours of continuing education on immunization and completed certification of immunization? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is there a Policy and Procedure manual on immunization? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are prescriptions or the physician-approved protocol current and available for inspection? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are all immunization patients counseled and given written information? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is a signed copy of patient immunization consent forms retained? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does documentation of each injection include all of the following? <ul style="list-style-type: none"> • Patient name, address, phone number Yes <input type="checkbox"/> No <input type="checkbox"/> • Patient DOB and gender Yes <input type="checkbox"/> No <input type="checkbox"/> • Name of medication administered, lot and expiration date Yes <input type="checkbox"/> No <input type="checkbox"/> • Administration site, dose, date of order and date of administration Yes <input type="checkbox"/> No <input type="checkbox"/> • Prescriber name Yes <input type="checkbox"/> No <input type="checkbox"/> • Name of pharmacist administering the injection Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Is all documentation retained for at least three years? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is documentation of vaccinations reported to the Division of Public Health Immunization Registry? Yes <input type="checkbox"/> No <input type="checkbox"/>	

DISPENSING PHARMACY Section 5.0 of the Pharmacy [Rules and Regulations](#)

27. Answer these questions about dispensing. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are automatic counting devices used in the pharmacy? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, does each cell have: <ul style="list-style-type: none"> • Name of drug Yes <input type="checkbox"/> No <input type="checkbox"/> • Manufacturer's name and NDC Yes <input type="checkbox"/> No <input type="checkbox"/> • Date filled Yes <input type="checkbox"/> No <input type="checkbox"/> • Batch/lot number and expiration date of the batch/lot Yes <input type="checkbox"/> No <input type="checkbox"/> 	

DISPENSING PHARMACY, Continued

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are all prescriptions maintained for a period of three years? Yes <input type="checkbox"/> No <input type="checkbox"/>	
When a generic drug is dispensed, is the manufacturer or distributor noted on the original prescription and the label? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are the initials of the filling/refilling pharmacist noted on the prescription and/or computer record? Yes <input type="checkbox"/> No <input type="checkbox"/>	

CONTROLLED SUBSTANCES [21 CFR 1300-1306](#)

28. Answer these questions about controlled substances. If your inspection found non-compliance, enter the corrective action taken and date of the corrective action in the last column.

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Are U.S. Official Order Form-Schedule II (DEA Form 222) (21 CFR 1305) and un-negotiated forms secure? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are the DEA Form 222s properly executed and retained for at least two years (21 CFR 1305.12)? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Regarding invoices of controlled substances (21 CFR 1304.04 f 1, 2): <ul style="list-style-type: none"> Are Schedule II order forms and invoices filed separately? Yes <input type="checkbox"/> No <input type="checkbox"/> Are Schedule III – V invoices signed and dated upon receipt and filed separately from other invoices? Yes <input type="checkbox"/> No <input type="checkbox"/> Are all invoices retained for at least two years? Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Regarding controlled substances that are returned for disposal (21 CFR 1307.21): <ul style="list-style-type: none"> Are the drugs returned for disposal via the reverse distributor? Yes <input type="checkbox"/> No <input type="checkbox"/> Are DEA Form 41 filed properly and retained for two years? Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Has there been any loss of controlled substances since the last review? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes , did you complete and submit a report of theft/loss of controlled substances to the Board and DEA (21 CFR 1301.76(b))? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Was a biennial inventory of controlled substances completed (21 CFR 1304.11c)? Yes <input type="checkbox"/> No <input type="checkbox"/> Date completed: _____	
Did the Pharmacist-in-Charge (PIC) change after the last self-inspection? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes , answer these questions: <ul style="list-style-type: none"> PIC Start Date _____ Was the Pharmacy Board notified about the PIC change within ten days and was a copy of the notification retained onsite? Yes <input type="checkbox"/> No <input type="checkbox"/> Did the departing and incoming PICs do a complete inventory of controlled substances, submit it to the Office of Controlled Substances and retain a copy onsite? Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Do prescriptions for controlled substances contain each of the following: <ul style="list-style-type: none"> Patient name and address Yes <input type="checkbox"/> No <input type="checkbox"/> Prescriber's name, address, phone number, and DEA # Yes <input type="checkbox"/> No <input type="checkbox"/> Date of issue Yes <input type="checkbox"/> No <input type="checkbox"/> Drug name, strength and quantity Yes <input type="checkbox"/> No <input type="checkbox"/> Specific directions Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Does the prescriber verify and authorize all verbal prescriptions for controlled substances? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Regarding Schedule II prescriptions: <ul style="list-style-type: none"> Filled separately from other prescriptions Yes <input type="checkbox"/> No <input type="checkbox"/> Filled within seven days of issue in a quantity of not more than 100 or a 31-day supply, whichever is greater Yes <input type="checkbox"/> No <input type="checkbox"/> Properly cancelled and signed by the filling pharmacist Yes <input type="checkbox"/> No <input type="checkbox"/> Not partially filled unless noted on the prescription that the patient is in a long-term care facility ("LTCF") or is "terminally ill" and not exceeding 60 days from issue? Yes <input type="checkbox"/> No <input type="checkbox"/> Listed in a perpetual inventory to audit on-hand quantities for accuracy? (Not a requirement) Yes <input type="checkbox"/> No <input type="checkbox"/> 	

CONTROLLED SUBSTANCES, Continued

INSPECTION QUESTION	CORRECTIVE ACTION/DATE
Regarding emergency filling of oral Schedule II prescriptions (21 CFR 1306.11(d)): <ul style="list-style-type: none"> Is the quantity dispensed limited to an amount adequate for the emergency situation? Yes <input type="checkbox"/> No <input type="checkbox"/> Is the term "Emergency Rx" written on the prescription? Yes <input type="checkbox"/> No <input type="checkbox"/> Is the written prescription from the prescriber received within seven days and attached to the oral prescription? Yes <input type="checkbox"/> No <input type="checkbox"/> 	
Are Schedule III prescriptions filled within seven days of issue? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are Schedule III-V prescriptions refilled more than five times or six months after issue? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the verification of person picking up controlled substances documented? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are OTC sales of pseudoephedrine products recorded in the log book? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is this pharmacy distributing controlled substances to other registrants including pharmacies, hospitals and practitioners? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, <ul style="list-style-type: none"> Are the Schedule II controlled substances distributed via DEA Form 222? Yes <input type="checkbox"/> No <input type="checkbox"/> Are the Schedule III-V controlled substances distributed via invoice? Yes <input type="checkbox"/> No <input type="checkbox"/> 	

CONTROLLED SUBSTANCES AUDIT

29. Complete a controlled substances audit for two drugs as directed by the Board. If a discrepancy is greater than 3%, you must submit a report to the Board within 30 days with an explanation.

DATE OF DRUG AUDIT: _____

NAMES OF DRUGS AUDITED	LAST INVENTORY	PURCHASES SINCE INVENTORY	SALES SINCE INVENTORY	CALCULATED QUANTITY (add Inventory and Purchases, then subtract Sales)	CURRENT INVENTORY	DISCREPANCY (subtract Current Inventory from Calculated Quantity)	% (divide Discrepancy by Calculated Quantity, then multiply by 100)
<i>Sample</i>	<i>300</i>	<i>700</i>	<i>600</i>	<i>400</i>	<i>350</i>	<i>50</i>	<i>12.5%</i>

CERTIFICATION

Delaware law holds the pharmacist-in-charge responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to do so could result in fines and/or actions against the pharmacy and/or pharmacist license.

I, _____, Delaware Pharmacist license # A1 - _____, hereby certify that I have completed the self-inspection of this pharmacy of which I am pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy and/or the Office of Narcotics & Dangerous Drugs. I further state under penalty of perjury that the information contained in this self-inspection form is true and correct to the best of my knowledge and belief.

Signature of Pharmacist-in-Charge: _____ **Date:** _____